

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.  
22-R-0040

CUSTOMER NO.  
689

FORM APPROVED  
OMB NO. 0579-0036

# ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

HUNTINGDON LIFE SCIENCES, INC.  
P.O. BOX 2360  
EAST MILLSTONE, NJ 08875  
(732) 873-2550

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

See Attached Listing

FACILITY LOCATIONS(sites)

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## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS  (Cols. C + D + E)
4. Dogs	0	749	129	18	896
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	347	31	13	391
9. Non-Human Primates	37	522	104	0	626
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

### ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

(b)(6), (b)(7)(c)

Type or Print)

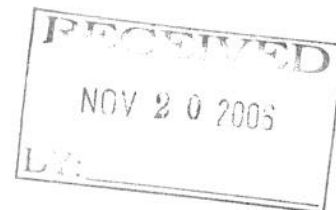
DATE SIGNED

11/16/06

(AUG 91)

(Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS



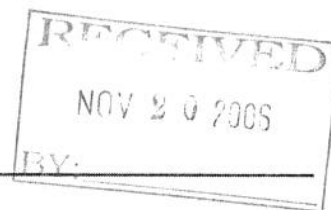
**A) Explanation of Category E Studies**

All studies listed were conducted to conform to federally mandated requirements, promulgated by the US Food and Drug Administration (FDA). These regulations specify pre-clinical testing requirements necessary for approval of new drugs. Specific regulations include the following:

- 21 CFR 310, New Drugs
- 21 CFR 312.22, Investigational New Drugs/Biologics
- 21 CFR 314, Application for FDA Approval to Market a New Drug or Antibiotic Drug
- International Conference on Harmonization (ICH) Guideline M3 on Non-Clinical Safety Studies for the Conduct of Human Clinical Trials in Pharmaceuticals – Guidance for Industry, US Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), 1997
- International Conference on Harmonization (ICH) Harmonized Tripartite Guideline (S5A): Detection of Toxicity to Reproduction for Medicinal Products, III/3387/93.
- International Conference on Harmonization (ICH) S3A: Guideline on the Assessment of Systemic Exposure in Toxicity Studies, 1994.
- FDA Part VI, Volume 61, No. 166, Single Dose Acute Toxicity Testing for Pharmaceuticals, August 1996.
- International Conference on Harmonization (ICH) S5B: Maintenance of the ICH Guideline on Toxicity to Male Fertility An Addendum to the ICH Tripartite Guideline on Detection of Toxicity to Reproduction for Medicinal Products
- OECD. 1998. Test Guideline 409. Repeated Dose 90-day Oral Toxicity Study in Non-rodents. In: OECD Guidelines for the Testing of Chemicals. Organisation for Economic Cooperation & Development.

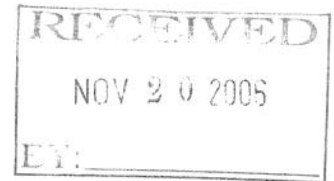
Species	Number of Category E Animals	Description
Dogs	2	Animals were exposed to test compound via oral gavage for one year. Test article effects were evident in 2 dogs. Consequently, these animals were humanely euthanized.
Dogs	2	Animals were exposed to test compound via oral capsule for 13 weeks. Test article effects were evident in 2 dogs. Consequently, these animals were humanely euthanized.
Dogs	1	Animals were exposed to test compound via oral gavage as a single dose (range finder), followed by 3 consecutive days of dose. Test article effects were evident in 1 dog. Consequently, this animal was humanely euthanized.
Dogs	3	Animals were exposed to test compound via oral gavage for one day. Test article effects were evident in 3 animals. These animals were humanely euthanized.

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Species	Number of Category E Animals	Description
Dogs	9	Animals were exposed to test compound via inhalation for approximately seven days. Test article effects were evident in 9 dogs. Animals were initially treated for these effects, and then humanely euthanized.
Dogs	1	Animals were exposed to test compound via inhalation for 1 day. Test article effects were evident in 1 dog. This animal was initially treated for these effects, and then humanely euthanized.
Rabbit	1	Animals were exposed to test compound via oral gavage for approximately 2 weeks. Test article effects were evident in 1 animal. This animal was humanely euthanized.
Rabbit	2	Animals were exposed to test compound via intravenous injection, for approximately two weeks. Test article effects were evident in 2 animals. Dosing was discontinued for one of these animals, and the second animal was humanely euthanized.
Rabbit	2	Animals were exposed to test compound via oral gavage for approximately 2 weeks. Test article effects were evident in two animals. Consequently, these animals were humanely euthanized.
Rabbit	1	Animals were exposed to test compound via oral gavage for approximately two weeks. Test article effects were evident in one animal. Consequently, this animal was humanely euthanized.
Rabbit	2	Animals were exposed to test compound via oral gavage for approximately 2 weeks. Test article effects were evident in 2 animals. Dosing was discontinued for one of these animals, and the second animal was humanely euthanized.
Rabbit	2	Animals were exposed to test compound via oral gavage for approximately 2 weeks. Test article effects were evident in 2 animals. These animals were humanely euthanized.
Rabbit	3	Animals were exposed to test compound via oral gavage for approximately 4 days. Test article effects were evident in 3 animals. These animals were humanely euthanized.

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**B) Summary of IACUC-approved exceptions to the Standards and Regulations:**

- 58 dogs were exempted from the exercise requirement for 14 days during surgical recovery for implantation of a telemetry implant, bile collection port, or vascular access port
- 1 dog was exempted from the exercise requirement for 10 days during surgical recovery for implantation of a subcutaneous telemetry implant.
- 11 dogs were exempted from the exercise requirement for 2 days for individual cardiovascular telemetry data collection.
- 1 dog was exempted from the exercise requirement for 3 days during individual cardiovascular telemetry data collection.
- 16 dogs were exempted from the exercise requirement for 6 days during individual cardiovascular telemetry data collection.
- 8 dogs were exempted from the exercise requirement for 8 days for individual cardiovascular telemetry data collection.
- 8 dogs were exempted from the exercise requirement for 10 days during individual cardiovascular telemetry data collection.
- 4 dogs were exempted from the exercise requirement for 18 days during individual cardiovascular telemetry data collection.
- 4 dogs were exempted from the exercise requirement for 23 days during individual cardiovascular telemetry data collection.